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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,708	04/03/2001	Ljerka Kunst	4810-58741	5955

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EXAMINER

BAUM, STUART F

ART UNIT PAPER NUMBER

2038

DATE MAILED: 02/10/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/806,708

Applicant(s)

KUNST ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1, 7, 13 and 15-38 is/are pending in the application.
- 4a) Of the above claim(s) 26-28 and 32-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1, 7, 13, 15-25 and 29-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

1. The amendment filed 11/25/02 has been entered.

Claims 1, 7, 13, 15-38 are pending.

Claims 29-38 have been added.

Claims 1 and 19 have been amended.

2. Newly submitted claims 32-38 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 32 recites sequences and sequence motifs that were not presented in the original claims and claims 33-38 are drawn to SEQ ID NO:22 which is a sequence not presented in the original claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 32-38 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 26-28 are withdrawn from consideration because they are drawn to non-elected inventions

4. This application contains claims 1, 7, 22, and 29-31 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancelation of nonelected sequences (37 CFR 1.144) See MPEP § 821.01.

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5. This application contains claims 26-28 and 32-38, drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

6. Claims 1, 7, 13, 15-25 and 29-31 are examined in the present office action.

7. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

8. Rejections and objections not set forth below are withdrawn.

### *Specification*

9. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code (see page 7, lines 1-33 from amendment filed 11/25/03). See MPEP § 608.01.

10. Applicant's election with traverse of Group I, claims 1, 7, 13, 15-23, and 25-28 including SEQ ID NO:15 is acknowledged. The traversal is on the ground(s) that the special technical feature shared by Groups I and II is the promoter sequence that hybridizes to nucleic acid molecules having a sequence of any of SEQ ID NO: 15, 16, 17 or 18. Applicants contend that the only prior art referred to in the Office action is Singh et al but that the special technical feature is not pointed out. Applicants also traverse the requirement to select one sequence and

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recite from the MPEP wherein it recites that ten sequences constitute a reasonable number for examination purposes.

This is not found persuasive because the purported special technical feature is a nucleic acid molecule that is capable of directing seed-specific expression in *Arabidopsis* and that hybridizes under stringent conditions to any one of SEQ ID NO:15, 16, 17, or 18. Singh et al (which should actually be cited as Sindhu et al) teach a seed-specific promoter, the glutelin seed storage promoter, which would hybridize to any one of SEQ ID NO 15-17 under stringent conditions given Applicants lack of explicitly stating said conditions. In regards to the requirement to elect one sequence, due to the ever increasing size of the nucleic acid databases, it is not feasible for the Office to search more than one nucleic acid sequence per application due to the available finite number of computers at the Offices disposal. In addition, because of the divergent nature of the nucleotide sequences of the different SEQ ID NO's, a search of one sequence will not cover a search of the other sequences.

The requirement is still deemed proper and is therefore made FINAL.

11. Claims 1, 7, 13, 15-25 and newly added claims 29-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 6/19/2002. Applicant's arguments have been fully considered but they are not persuasive.

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Applicants submit that it is not necessary to identify structural features unique to the 393 base pairs of SEQ ID NO:15. Applicants recite guidelines as stated in the "Guidelines for Examination of Patent Applications" and contend that they have complied with the guidelines so as to be in possession of their invention. In particular, they disclose SEQ ID NO:16 and assert that the disclosure is sufficient for claims drawn to sequences exhibiting at least 70% identity to SEQ ID NO:15. Applicants conclude by stating "Applicants have provided the ultimate written description of the claimed invention -- the nucleotide sequence" (page 13, 1<sup>st</sup> paragraph).

The Examiner agrees that a submission of a sequence is an adequate written description but only for claims drawn to the entire sequence (emphasis added). For claims, broadly drawn to a sequence exhibiting at least 70%, 80%, 90%, 95% or even 99% identity to SEQ ID NO:15, Applicant is required to describe distinguishing identifying characteristics (as stated in the paragraph that Applicants recites from "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1 'Written Description' Requirement") and to describe the functional domains of the sequence so that one of skill in the art will know which regions of the sequence cannot be altered and which regions can tolerate base changes and still have a sequence that functions like SEQ ID NO:15.

12. Claims 1, 7, 13, 15-25 and newly added claims 29-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to 393 bp's from the *Arabidopsis FAE1* promoter to obtain seed-specific expression of a GUS reporter gene in *Arabidopsis*, does not reasonably provide enablement for claims broadly drawn to sequences that hybridize under stringent conditions to SEQ ID NO:15, or sequences that are 70% or 80%

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identical to SEQ ID NO:15 and drawn to plant transformation with the exemplified or non-exemplified promoter fragment to obtain seed-specific expression. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 6/19/2002. Applicant's arguments have been fully considered but they are not persuasive.

Applicants contend that both the 393 bp region and the 934 bp region of the *Arabidopsis* FAE1 promoter are functional for directing expression in seeds (see page 13, lines 16-19). Applicants further contend that one skilled in the art would be able to use additional promoter regions that are either 70%-80% identical to SEQ ID NO:15 or that hybridize to SEQ ID NO:15 without undue experimentation. Applicants also contend that the previous action mailed 6/19/2002 asserted that it would require undue experimentation by one skilled in the art to **predict** [sic] which recombinant nucleic acid molecules could be used to alter the phenotype of a seed upon transformation. Applicants submit that no prediction is necessary, rather one skilled in the art could simply assess the activity of a particular molecule as taught in the specification. Applicants conclude by stating that they are not just claiming a promoter, but, rather, a promoter that comprises a "transcriptional regulatory region capable of mediating seed-specific expression in *Arabidopsis*" (page 16, 2<sup>nd</sup> paragraph). Applicants lastly point out that the specification teaches how to assay for promoter activity.

The Examiner agrees that the specification is enabling for both the 393 bp region and the 934 bp region of the *Arabidopsis* FAE1 promoter. But, the specification does not disclose sequences that are at least 70% identical to SEQ ID NO:15 or that hybridize to SEQ ID NO:15.

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Applicant has not taught which regions of the promoter can be altered or deleted and still maintain the proper activity. Given the variability of plant transformation, the multitude of sequences that can possibly be tested and the number of plants that have to be examined, it would require undue experimentation by one skilled in the art to make or use the broadly claimed invention.

13. No claims are allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.



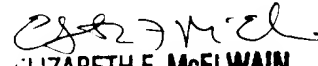
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, who may be contacted at 308-0196.

Stuart F. Baum Ph.D.

February 5, 2003

  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1600